

Detection Systems for Biological and Chemical Countermeasures (DSBCC)

Biological Countermeasures (TTA-1 & TTA-2)

DSBCC – RA03-01

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DSBCC – Biological Countermeasures

- TTA-1 Bioagent Autonomous Networked Detectors (BAND)
 - Develop Next Generation Bio-surveillance Sensor System to Enable Wider Coverage with Reduced Cost
 - Focused on Detect-to-Treat Mission
- TTA-2 Rapid Automated Biological Identification System (RABIS)
 - Develop Fast, Low False Alarm Detector System
 - Enabling Technology for Detect-to-Treat Strategies
 - Extremely Challenging Goals
- Strong Focus on Technology Selection/Development that Dramatically Reduces Cost of Ownership
 - Reduce Purchase Cost in Units of 100s to 1000s
 - Dramatically Reduce Cost of Operation



Outline

- Rationale for Technical Topic Area
- System Performance Goals
- Key Technical Challenges
- Program Schedule, Phases & Funding
- Deliverables
- White Paper & Proposal Guidance
- Some Frequently Asked Questions



Technical Topic Area 1 (TTA-1)

Bioagent Autonomous Network Detector (BAND)



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Rationale for TTA-1 (BAND)

- Bioagent Autonomous Network Detector (BAND)
 - Detect-to-Treat Biological Surveillance Sensor System
 - Build on Current Biowatch Architecture
- Current Biowatch System Exploits Distributed Collector Systems with Centralized Evaluation of Samples
 - Current Approach Limits Timeliness of Response
 - Current Approach Limits Spatial-Temporal Coverage Granularity
 - Current Approach Driven by Large Logistical and Labor Costs
- BAND Will Permit Extending Breadth of Coverage in Threat Space and Increasing Spatial-Temporal Coverage
 - Must Significantly Reduce Total System Operating Costs



TTA-1 Goals – Performance Targets

- Continuous, Fully Autonomous Operation with 3 Hour Sample Intervals and 1 Hour Latency (2920 Samples per Year)
- Broad Agent Coverage > 20 Agents
 - Spore, Vegetative Cell, Toxin, DNA Virus, RNA Virus
- High Sensitivity – Limit of Detection (LOD) of 100 Organisms
 - Assumes 3 Hour, 100 Liter/Minute, 90% Efficient Collection
 - Performers Free to Scale to Alternative Approaches
 - LOD of 10 nanograms for Toxins
- Single Agent False Positive Rate of 10^{-7} with a goal of 10^{-8}



TTA-1 Goals – Cost of Ownership

- BAND Unit Acquisition Cost of \$25K per Unit or Less
 - Assume Quantities of 1,000s
- BAND Operating Costs per Unit of \$10K per Year or Less
 - Inclusive of all Costs: Consumables, Maintenance, Spare Parts, etc.



TTA-1 Goals – System Characteristics

- Preserve Samples for 5 Days
 - Confirmation and Forensics
- Robust Wireless, Autonomous Remote Operation
- Maintenance Interval Exceeding 1 Month
- Operation in Full Range of Outdoor Environments
- Modest Packaging and Logistical Requirements
 - (Ex: 2 cubic feet Volume)



Key Technical Challenges

- Very High Sensitivity in Cluttered Background
- Extending Breadth of Threat Coverage (>20)
 - Either Multiplexed Testing or Large Number of Tests
- Achieving Very Low False Alarm Rate
 - Single BAND System P_{fa} in the Range of 1 per 10 to 100 Years
 - Proliferation of BAND Systems Requires Low Single System P_{fa}
- Achieving Low Cost of Ownership
 - Single Sample Cost Goal of ~ \$3.50 per Test (Multiplexed)
 - Single Sample, Single Agent Cost Goal of ~ \$0.17 per Test (Non-Multiplexed)



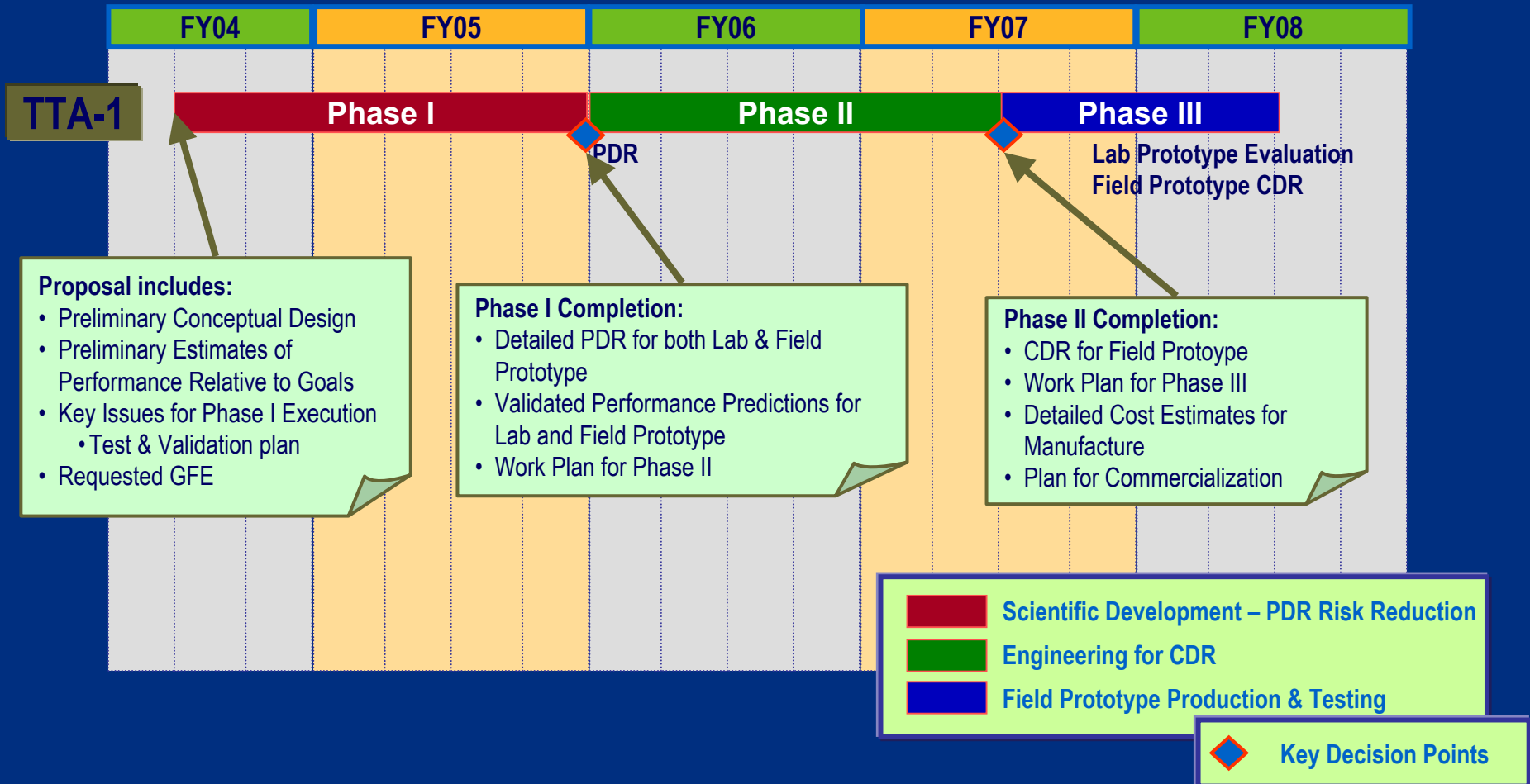
Priorities

- Performance, Cost of Ownership & System Characteristics are Goals - Order of Priority:
 - 1) Performance
 - 2) Cost of Ownership
 - 3) System Characteristics
- Bidders are Encouraged to Meet Greatest Number of Goals in Order of Priority
 - Explain Key Technical Issues Required to Meet Each Goal
 - Explain Key Technical Issues for Goals Which Can Not be Met
- White Papers and Proposals Which Meet a Majority of Goals are Encouraged



Notional Program Schedule

Bidders are encouraged to provide accelerated schedule if possible



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Funding

- Multiple Phase I Awards Anticipated
- Anticipated Upper Value of Phase I Awards of \$4.5M
 - Proposals will be Evaluated for Cost Realism
 - Proposals will be Selected Based upon Best Value to the Government
- Multiple Phase II/III Awards Possible



Deliverables

- Phase I PDR for both Laboratory and Field Prototypes
 - Analysis of Performance Relative to Goals
 - Enumerate Differences in Performance for Laboratory (Phase II) and Field (Phase III) Prototypes
 - Provide Plan for Migration from Laboratory to Field Prototype
- Performance Targets
 - Validate Sensitivity
 - Include Validations/Calculations for full Range of Potential Threats
 - Provide Scientifically Credible Validation of P_{fa} Performance
 - Provide Estimates of Cost of Ownership
 - Must Include Detailed Estimate for Operations Including Consumables



White Paper Guidance (6 pages)

- Preliminary Description of System Concept
 - Provide Basis for Technology Selection & Identify Key Technical Challenges
 - Include Preliminary Description of System Characteristics
- Preliminary Estimates of Performance Relative to Goals
 - Preliminary Estimate of Sensitivity
 - Plan for Validating Sensitivity for Full Range of Potential Threats
 - Preliminary Estimate of P_{fa} Performance
 - Plan for Validating P_{fa}
- Preliminary Estimates of Cost of Ownership
 - Both Unit Cost and Cost of Operations Including Consumables
- Identify Any Resources to be Requested from the Government



Proposal Guidance

- Provide Description of System Concept
 - Provide Basis for Technology Selection
 - Provide Plan for Resolution of Key Technical Challenges
 - Provide Preliminary Description of the System Characteristics for Both the Laboratory (Phase II) and Field (Phase III) Prototypes
- Provide Analysis of Performance Relative to Goals
 - Estimate of Sensitivity for Full Range of Potential Threats
 - Plan for Validating Sensitivity for Full Range of Potential Threats
 - Estimate of and Plan to Validate P_{fa} Performance
 - Estimates of Cost of Ownership
 - Include Detailed Estimate for Operations Including Consumables
 - Enumerate Anticipated Differences in Laboratory (Phase II) and Field (Phase III) Prototypes



Some Frequently Asked Questions

- **In the RA you mention listing any expectations for Government furnished resources – what resources are available and what constraints and requirements accompany the use of these resources?**

Given the breadth of potential responses to this solicitation, we have not attempted to anticipate potential requests, but we are prepared to collaborate with other government agencies and programs to make available resources such as sequence data, probe sequence data and probe material, antibodies, simulant, threat and background test material and bioaerosol test facilities. Please provide requests for resources to the FAQ website as well as include your specific requests in your white paper.



Some Frequently Asked Questions

- **Are Teams expected to develop the assays for the full set of 20 or more threats as part of this effort?**

Teams may request, as part of their GFE, assays such as nucleic acid probe sets or antibodies. For novel approaches, Teams may need to include as part of their work plan assay development and validation.



Technical Topic Area 2 (TTA-2)

Rapid Automated Biological Identification System (RABIS)



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Rationale for TTA-2 (RABIS)

- Rapid Automated Biological Identification System (RABIS)
 - Detect-to-Protect Biological Surveillance Sensor System
 - Enable New Paradigms in Biodefense
 - Building Protection Architecture
 - Selected Outdoor Event Coverage
- Detect-to-Protect Requires
 - Very Fast Response Time (< 2 Minutes)
 - Very Low False Alarm Rates
 - Broad and Sensitive Threat Coverage
- TTA-2 May Require Significant Innovation
 - **Extraordinarily Challenging Technical Goals**



TTA-2 Goals – Performance Targets

- Continuous, Fully Autonomous Operation with 2 Minute or Shorter Sample Intervals Including Latency
 - ~250K Samples per Year
- Broad Agent Coverage > 20 Agents
 - Spore, Vegetative Cell, Toxin, DNA Virus, RNA Virus
- Limit of Detection (LOD) of 100 Organisms per Liter of Air
 - LOD of 0.05 nanograms per Liter of Air for Toxins
- System False Alarm Rate of No More than Once per Month
 - Goal to Reduce System False Alarm Rate < 1 Year



TTA-2 Goals – Cost of Ownership

- RABIS Unit Acquisition Cost of \$50K per Unit or Less
 - Assume Quantities of 100s

- RABIS Operating Costs per Unit of \$20K per Year or Less
 - Inclusive of all Costs: Consumables, Maintenance, Spare Parts, etc.



TTA-2 Goals – System Characteristics

- Preserve Positive Samples
 - Confirmation and Forensics
- Robust Wireless, Autonomous Remote Operation
- Maintenance Interval Exceeding 1 Month
- Operation in Full Range of Indoor and More Limited Outdoor Environments
- Modest Packaging and Logistical Requirements
 - (Ex: 2 cubic feet Volume)



Key Technical Challenges

- Combined Goals of Short Response Time with High Selectivity
 - **Likely to Require Significant Innovation**
- Short Sample Interval Exacerbates Technical Challenges to Achieve Low System False Alarm Rates
 - Approximately 250K Threat-Multiplexed Tests per Year
- Short Sample Interval Exacerbates Technical Challenges to Achieve Low Cost of Ownership
 - Multiplexed (or Broadband) Single Interval Test Cost of ~ \$0.08



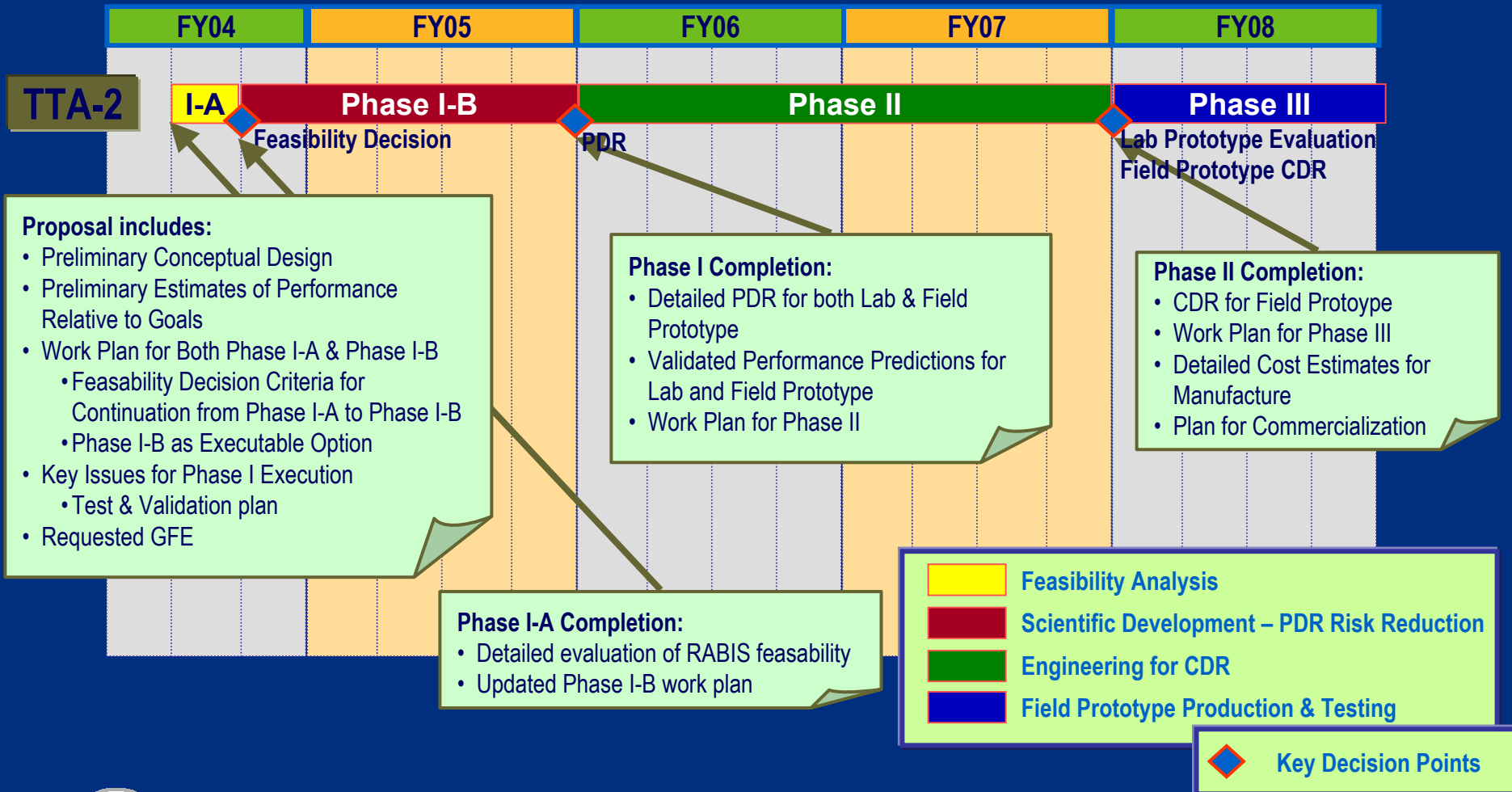
Priorities

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 - 3) System Characteristics
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 - Explain Key Technical Issues Required to Meet Each Goal
 - Explain Key Technical Issues for Goals Which Can Not be Met
- White Papers and Proposals Which Meet a Majority of Goals are Encouraged



Notional Program Schedule

Bidders are encouraged to provide accelerated schedule if possible



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Funding

- Multiple Phase I-A Awards Anticipated
 - Anticipated Value of Phase I-A Awards of \$250K
- Proposal Should Cost Phase I-A and Phase I-B Separately
 - Proposals will be Evaluated for Cost Realism
 - Proposals will be Selected Based Upon Best Value to the Government
- Phase I-B Should be Structured as an Option to Phase I-A Work Plan
 - There will be an Opportunity to Update the Phase I-B Work Plan and Costs Proposal During Phase I-A
- Phase I-A Feasibility Analysis May Result in Zero, One or Multiple Phase 1-B Awards



Deliverables

- Phase I-A
 - Analysis of Feasibility of Achieving RABIS Goals
 - Updated Phase I-B Work Plan
- Phase I-B PDR for Both Laboratory and Field Prototypes
 - Analysis of Performance Relative to Goals
 - Enumerate Differences in Performance for Laboratory (Phase II) and Field (Phase III) Prototypes
 - Provide Plan for Migration from Laboratory to Field Prototype
- Performance Targets
 - Validate Sensitivity and Response Time
 - Provide Scientifically Credible Validation of P_{fa} Performance
 - Provide Estimates of Cost of Ownership



White Paper Guidance (6 pages)

- Preliminary Description of System Concept
 - Provide Basis for Technology Selection
 - Identify Key Technical Challenges/Innovations Required to Achieve Goals
 - Include Preliminary Description of System Characteristics
- Preliminary Estimates of Performance Relative to Goals
 - Preliminary Estimate of Sensitivity and Response Time
 - Preliminary Estimate of P_{fa} Performance Including Validation Plan
- Preliminary Estimates of Cost of Ownership
- Define Suggested Phase I-A Feasibility Decision Criteria
- Identify Any Resources to be Requested from the Government



Proposal Guidance

- Provide Description of System Concept
 - Provide Basis for Technology Selection
 - Provide Plan for Resolution of Key Technical Challenges
 - Provide Preliminary Description of the System Characteristics
- Provide Analysis of Performance Relative to Goals
 - Estimate of Sensitivity for Full Range of Potential Threats
 - Plan for Validating Sensitivity for Full Range of Potential Threats
 - Estimate of and Plan to Validate P_{fa} Performance
 - Estimates of Cost of Ownership
 - Include Detailed Estimate for Operations Including Consumables
- Enumerate Goals of Phase I-A Feasibility Analysis
 - Propose Decision Criteria for Phase I-A to Phase I-B Evaluation



Some Frequently Asked Questions

- **The Limit of Detection is specified as 100 organisms per liter of air – is there an assumed air collection rate?**

The notional collection rate is 100 liters per minute with 90% efficiency. Bidders are welcome to propose different air collection/concentration rates.

- **What if we anticipate only meeting a sub-set of the RABIS goals?**

White papers which have the potential to meet a significant sub-set of the RABIS goals are strongly encouraged.

